

UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY

CHAMBERS OF  
MICHAEL A. SHIPP  
UNITED STATES MAGISTRATE JUDGE

MARTIN LUTHER KING COURTHOUSE  
50 WALNUT ST. ROOM 2042  
NEWARK, NJ 07102  
973-645-3827

Not for Publication

LETTER OPINION AND ORDER

August 4, 2010

VIA CM/ECF

All counsel of record

**Re: Hoffmann-La Roche Inc. v. Cobalt Pharmaceuticals, Inc. et al.  
07-4539 (SRC)(consolidated with Case Nos. 07-4540 (SRC) & 08-4054 (SRC))**

Dear Counsel:

This matter comes before the Court by way of Defendants Cobalt Pharmaceuticals, Inc. and Cobalt Laboratories, Inc.'s (collectively, "Defendants" or "Cobalt") Motion for Leave to Amend their Answer to Assert Improper Inventorship. (Docket ("Doc.") No. 189.) Plaintiff Hoffmann-La Roche Inc. ("Plaintiff" or "Roche") opposes the motion. (Doc. No. 194.) For the reasons set forth below, Defendants' motion is granted, subject to the provisions enumerated below.

**I. Background**

As the parties are well-versed on the facts surrounding this matter, the Court will address only those facts relevant to the motion currently pending before this Court.

In its November 28, 2007 and January 19, 2009 Answers, Defenses and Counterclaims, Cobalt pled the defense that the claims "are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Patent Code, and/or for

obviousness-type double patenting.” (Doc. No. 12 at 19.) Cobalt asserted that the within patent case is subject to the general notice pleading standards of Federal Rule of Civil Procedure 8(b)(1). (Defs.’ Moving Br. 1.) Cobalt stated that it previously placed Roche on notice that it would challenge the validity of the patents-in-suit for failure to comply with statutory patentability requirements pursuant to 35 U.S.C. §§ 101, 102, 103 and 112. 35 U.S.C. § 102(f) includes improper inventorship. (*Id.*) Roche responded that Cobalt did not specifically plead a 35 U.S.C. § 102(f) improper inventorship defense and asserted that Cobalt’s request to add the defense was untimely. (Pl.’s Opp’n Br. 2.) After having considered the initial briefs, the Court found that the briefs lacked sufficient information and argumentation regarding the issues of undue delay and undue prejudice. Therefore, the Court required counsel to submit supplemental briefs on those issues. The Court’s April 29, 2010 Letter Order specifically provided:

By May 5, 2010, Roche must file a letter brief on the issue of undue delay and undue prejudice which concentrates on the issue of the discovery that would be required and the time frame for the discovery should the Court grant Cobalt’s motion to amend. Counsel should include citations to relevant legal authority.

By May 10, 2010, Cobalt must file a responsive brief on the issue of undue delay and undue prejudice. Counsel should include citations to relevant legal authority.

(Doc. No. 222.) Counsel completed their supplemental briefing. Unfortunately, the supplemental briefs still do not fully clarify the scope and time frame of the discovery that would be required should the Court grant the motion to amend. The parties continue to take opposite positions as to undue delay and undue prejudice. The Court will consider those positions in light of the liberal standard set forth by the Third Circuit.

## II. Discussion

Federal Rule of Civil Procedure 15(a)(1) establishes that “[a] party may amend its pleading once as a matter of course within: (A) 21 days after serving it; or (B) if the pleading is one to which a responsive pleading is required, 21 days after service of a responsive pleading or 21 days after service of a motion under Rule 12(b), (e), or (f), whichever is earlier.” Otherwise, according to Rule 15(a)(2) “a party may amend its pleading only with the opposing party's written consent or the court's leave. The court should freely give leave when justice so requires.”

“The grant or denial of leave to amend is a matter committed to the sound discretion of the district court.” *Arab African Int'l Bank v. Epstein*, 10 F.3d 168, 174 (3d Cir. 1993). The Third Circuit has adopted a particularly liberal approach to the amendment of pleadings in order to ensure that “a particular claim will be decided on the merits rather than on technicalities.” *Dole v. Arco Chem. Co.*, 921 F.2d 484, 487 (3d Cir. 1990). Thus, “[a] general presumption exists in favor of allowing a party to amend its pleadings.” *Del Sontro v. Cendant Corp.*, 223 F. Supp. 2d 563, 576 (D.N.J. 2002). In addition, the need for amended summary judgment motions or additional discovery does not constitute sufficient grounds to deny a motion to amend. *Dole*, 921 F.2d at 488.

Leave to amend may be denied where the Court finds: (1) undue delay; (2) undue prejudice to the non-moving party; (3) bad faith or dilatory motive; or (4) futility of amendment. *Foman v. Davis*, 371 U.S. 178, 182 (1962); *Alvin v. Suzuki*, 227 F.3d 107, 121 (3d Cir. 2000). The Court does not find bad faith or dilatory motive or futility of amendment. Accordingly, the Court will address the issues of undue delay and undue prejudice in turn.

**A. Undue Delay**

A court may deny a motion to amend if the movant's delay in seeking the amendment is undue. *Foman*, 371 U.S. at 182. "The mere passage of time does not require that a motion to amend . . . be denied on grounds of delay. In fact, delay alone is an insufficient ground to deny leave to amend." *Cureton v. Nat'l Collegiate Athletic Ass'n*, 252 F.3d 267, 273 (3d Cir. 2001) (internal citation omitted). However, if the delay places an unwarranted burden on the court or on the opposing party, then denial based on delay is appropriate. *Adams v. Gould Inc.*, 739 F.2d 858, 868 (3d Cir. 1984).

In the present case, Roche argues undue delay from Cobalt based on a number of factors. First, fact discovery closed on June 26, 2009 after two extensions were granted, during which Cobalt took the depositions of all fact witnesses related to the inventorship issue. (Pl.'s 5/5/10 Ltr. 3.) Despite having questioned the deponents on the issue and having received factual information, Cobalt failed to seek leave to file an amended pleading related to inventorship. (*Id.*) In addition, Roche points to instances throughout the past year of litigation where Roche asserted that improper inventorship is not an issue in the case because Cobalt failed to plead improper inventorship as a defense. (*Id.*) In sum, Roche asserts:

[E]ven with a discovery deadline of June 26, 2009, the repeated opportunities afforded for Cobalt to raise and seek leave to file amended pleadings, and Roche's notice that this was an affirmative defense that required leave to be pleaded, nonetheless Cobalt did not file a motion related to the '814 patent until it was ordered to do so by the Court.

(*Id.* at 6.)

Cobalt asserts that it did not exercise undue delay when it filed its motion to amend after specific instructions from the Court. Cobalt argues that it "long ago" issued interrogatories to



Roche requesting that Roche substantiate its contentions as to why the patents-in-suit are valid. (Defs.' 5/12/10 Ltr. 2-3.) In addition, Cobalt asserts that it satisfied its notice and pleading obligations because it originally pled invalidity as an affirmative defense and "[a]ny additional defenses or counterclaims that discovery may reveal." (*Id.* at 4.) Cobalt states that it promptly raised its inventorship defenses in its interrogatory responses shortly after it deposed the named inventors. (*Id.* at 4-5.) According to Cobalt, Roche has been on notice that Cobalt would raise this defense before both the close of fact discovery and the commencement of expert discovery. (*Id.* at 5.) Finally, Cobalt notes that there is a strong policy within the Third Circuit in favor of allowing amended pleadings, and case management concerns alone are insufficient to reject a motion to amend. (Defs.' Moving Br. 12, 18; Defs.' 5/12/10 Ltr. 2, n.3.)

The Court must consider the issue of undue delay in light of the nature of the improper inventorship affirmative defense. "Affirmative defenses to infringement include noninfringement, unenforceability, [and] invalidity (e.g., failing to satisfy the written description or enablement requirements)." *Monsanto Co. v. Scruggs*, 459 F.3d 1328, 1334 (Fed. Cir. 2006) (citing 35 U.S.C. § 282). 35 U.S.C.A. § 282 provides, in part: "[t]he following shall be defenses in any action involving the validity or infringement of a patent and shall be pleaded: . . . (2) Invalidity of the patent or any claim in suit on any ground specified in part II of this title as a condition for patentability." "Section 102, which is within Part II of Title 35, is entitled 'Conditions for patentability; novelty and loss of right to patent'; section 102(f) provides that '[a] person shall be entitled to a patent unless he did not himself invent the subject matter sought to be patented.'" *Pannu v. Iolab Corp.*, 155 F.3d 1344, 1348-49 (Fed. Cir. 1998) (citing 35 U.S.C. § 102(f)).

Notably, a party is not put on notice of an affirmative defense based on discovery requests or the fact that a party's own documents contain information sought to be used as evidence for the affirmative defense. *Daiichi Pharm. Co. v. Apotex, Inc.*, No. 03-937, 2005 U.S. Dist. LEXIS 26059, at \*8 (D.N.J. Nov. 1, 2005), *rev'd on other grounds*, 501 F.3d 1254 (Fed. Cir. 2007). The complex nature of the claim analysis justifies the need for affirmative defenses to be pleaded early. *Id.* Furthermore, bare allegations of invalidity establishing an affirmative defense, such as responses to discovery or reservations to assert further claims, will not serve as notice. *See Advanced Cardiovascular Sys., Inc. v. Medtronic, Inc.*, 265 F.3d 1294, 1303-04 (Fed. Cir. 2001). However, certain circuits have held that the prejudice or surprise that Federal Rule of Civil Procedure 8(c) seeks to avoid can be reduced under certain circumstances. Such circumstances include instances where the defendant reserved the right to raise additional defenses, the issue was introduced during the parties' own depositions and/or the court afforded the plaintiff the opportunity to fully brief and rebut the tardily raised affirmative defense. *See Creative Consumer Concepts, Inc. v. Kreisler*, 563 F.3d 1070 (10th Cir. 2009).

The Court is concerned that Cobalt only brought its motion to amend after specific instructions from the Court. Cobalt acknowledges that improper inventorship is an affirmative defense. In its moving brief, Cobalt states:

Specifically, Cobalt seeks to assert an affirmative defense and counterclaim of invalidity on the ground that discovery obtained after the original pleading-amendment deadline revealed facts establishing that at least Dr. Elmar Bosies is not a proper inventor of the subject matter claimed by the '814 patent; and that the '938 and '957 patents likewise fail to properly reflect the names of those who conceived of the claimed invention.

(Defs.’ Moving Br. 1.) In conferences with the Court, Roche clearly enunciated its belief that improper inventorship was not pleaded and, therefore, not at issue in the case. While Cobalt set forth a number of arguments regarding the timing behind its filing of the motion to amend, Cobalt’s arguments do not adequately account for the length of the delay. At the very least, Cobalt could have filed a motion to amend to allege improper inventorship during the same time frame it filed its motion to amend for invalidity in late August 2009. Cobalt failed to do so and the Court finds undue delay under the facts of the present case. Nevertheless, delay alone is not sufficient ground to deny a motion to amend. Therefore, the Court will turn to the undue prejudice factor.

**B. Undue Prejudice**

Prejudice to the non-moving party constitutes “the touchstone for the denial of leave to amend.” *Heyl & Patterson Int’l, Inc. v. F. D. Rich Hous. of V.I., Inc.*, 663 F.2d 419, 425 (3d Cir. 1981) (quoting *Cornell & Co., Inc. v. Occupational Safety & Health Review Comm’n*, 573 F.2d 820, 823 (3d Cir. 1978)). The burden of establishing prejudice rests with the non-moving party, who must demonstrate that permitting the moving party to amend the pleading “would: (i) require the opponent to expend significant additional resources to conduct discovery and prepare for trial; (ii) significantly delay the resolution of the dispute; or (iii) prevent the plaintiff from bringing a timely action in another jurisdiction.” *Long v. Wilson*, 393 F.3d 390, 400 (3d Cir. 2004); *see also Textron Fin.-N.J., Inc. v. Herring Land Group, LLC*, No. 06-2585, 2009 WL 690933, at \*4 (D.N.J. Mar. 11, 2009). “Delay alone . . . does not justify denying a motion to amend. Rather, it is only where delay becomes ‘undue, placing an unwarranted burden on the court, or . . . prejudicial, placing an unfair burden on

the opposing party' that denial of a motion to amend is appropriate." *Textron Fin.-N.J., Inc.*, 2009 WL 690933, at \*4 (quoting *Adams*, 739 F.2d at 868).

The amount of additional resources that the non-moving party must expend to conduct discovery largely depends on the nature of the added claim or affirmative defense. "[M]isjoinder or nonjoinder of inventors," also stated as improper inventorship, "must be proven by facts supported by clear and convincing evidence." *Trovan, Ltd. v. Sokymat SA, Irori*, 299 F.3d 1292, 1301 (Fed. Cir. 2002). Furthermore, "[b]ecause co-inventors need not make a contribution to the subject matter of every claim of the patent, inventorship is determined on a claim-by-claim basis." *Id.* at 1302 (citing 35 U.S.C. § 116) (internal quotations omitted). The Federal Circuit has found the analysis for improper inventorship to include two steps:

[A]n inventorship analysis, like an infringement or invalidity analysis, begins as a first step with a construction of each asserted claim to determine the subject matter encompassed thereby. . . . The second step is then to compare the alleged contributions of each asserted co-inventor with the subject matter of the properly construed claim to then determine whether the correct inventors were named.

*Id.* (internal citations omitted.)

Plaintiff argues that the proposed amended complaint will cause undue prejudice. Plaintiff relies on *Daiichi Pharmaceutical Company* and argues that an affirmative defense, such as improper inventorship, involves a "complex analysis." (Pl.'s Opp'n Br. 28, citing No. 03-937, 2005 U.S. Dist. Lexis 26059, at \*11.) Plaintiff contends that it has not received an answer from Cobalt as to which inventors and claims Cobalt wishes to address with regard to the improper inventorship defenses. (Pl.'s Opp'n Br. 31-33.) Because Plaintiff did not receive requested information from Cobalt, Plaintiff did not specify the exact discovery or amount of time required



for further discovery in the event that the request for leave to amend is granted. (Pl.'s 5/14/10 Ltr. 5.) Rather, Plaintiff generally asserts that the amount of discovery would be "extensive." (Pl.'s Opp'n Br. 27-34.)

Plaintiff also notes that the extent of the discovery would depend on the identification of individuals and claims at issue linked to the defense of improper inventorship, and that Plaintiff would be entitled to perform a "complex analysis" with regard to each of these. (Pl.'s 5/14/10 Ltr. 5.) In addition, Plaintiff asserts that the parties must reopen fact and expert discovery so that the parties can re-depose Roche employees and experts to better prepare for possible arguments that could be asserted by Cobalt at trial. (Pl.'s 5/5/10 Ltr. 8, 11.) Plaintiff also asserts that counsel must reopen claim construction and summary judgment briefing. (*Id.* at 11.)

On the other hand, Cobalt argues that Plaintiff will not be unduly prejudiced by the improper inventorship affirmative defense since all of the witnesses and documents are within Plaintiff's control. (Defs.' Moving Br. 20; Defs.' 5/12/10 Ltr. 6-7.) Further, Cobalt notes that any information which it intends to use at trial is already part of the record and no surprise can arise from the defense. (Defs.' 5/12/10 Ltr. 7.)

The Court finds that Plaintiff raises legitimate concerns regarding the need for potentially broad and extensive discovery. However, while Plaintiff asserted legitimate concerns regarding the undue prejudice issue, the Court does not find undue prejudice based on the specific representations made by Defendants, including:

Cobalt does not plan to introduce new expert reports specific to the issue of inventorship if its motion to amend is granted. Nor does Cobalt see the need for any further claim construction or summary judgment briefing . . . . There will be no further delay introduced into the present schedule.

(Defs.' 5/12/10 Ltr. 3.) Plaintiff did not convince the Court that undue prejudice will result from the amendment. While the Court is still not clear regarding the exact discovery that will be necessary if it grants Defendants' motion to amend, it was Plaintiff's burden to demonstrate the prejudicial nature of Defendants' proposed amendment. Based on the liberal standard set forth by the Third Circuit, the undersigned finds that Plaintiff did not meet its burden. Indeed, any burden related to discovery and reexamination of Plaintiff's employees that may result from the amended pleading is lessened by the fact that they are in Plaintiff's control. Accordingly, Cobalt's motion to amend is granted.

Significantly, the Court grants Cobalt's motion to amend based, in part, on Cobalt's representations that granting the motion will not result in delay. In conjunction with this Opinion and Order, the Court will require an expedited schedule for discovery related to the amended answer.<sup>1</sup> Should it become clear in practice that the discovery required is overly extensive and will result in prejudice to the Plaintiff, the Court will consider an appropriate request for relief from Plaintiff.

### **III. Conclusion**

Based on the foregoing and for good cause shown, it is **ORDERED** that:

1. Cobalt's motion to amend is granted. Cobalt must file its amended pleading by **August 9, 2010.**
2. All discovery related to the amended answer must be completed by **August 31, 2010.**

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<sup>1</sup> As previously discussed, Cobalt brought this motion considerably late in the case. Therefore, the Court expects Cobalt to fully cooperate and comply with an expedited discovery schedule.

3. Counsel must meet and confer immediately regarding the discovery requests related to the amended answer. By **August 12, 2010**, counsel must submit a detailed joint proposed expedited discovery schedule that clearly lists the discovery required and the dates of completion, with discovery to be completed by **August 31, 2010** (as set forth above).
4. This matter is scheduled for a telephone status conference on **August 13, 2010 at 4:30 p.m.** Counsel for Cobalt shall initiate the call to (973) 645-3827.

s/ Michael A. Shipp  
**HONORABLE MICHAEL A. SHIPP**  
**UNITED STATES MAGISTRATE JUDGE**